Program Project Description:

Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA has significant responsibilities for ensuring that chemicals in or entering commerce do not present unreasonable risks to human health or the environment. These responsibilities are executed by the Agency through the Chemical Risk Review and Reduction (CRRR) Program, which works to ensure the safety of:

- Existing chemicals (those already in use when TSCA was first enacted in 1976 and those which have since gone through review by the TSCA New Chemicals Program),[1] by obtaining and evaluating chemical data and by taking regulatory action, where appropriate, to prevent any unreasonable risk posed by their use; and

- New chemicals by reviewing new chemical notices submitted by industry, including Pre-Manufacture Notices (PMNs), and taking action, as appropriate, to ensure that no unreasonable risk will be posed by such chemicals upon their entry into U.S. commerce.

The amended TSCA law, signed on June 22, 2016, provided EPA with significant new authorities and obligations:

- *Clear and enforceable deadlines.* EPA is required to systematically prioritize and evaluate existing chemicals on a specific schedule, complete specified numbers of chemical risk evaluations within specified time frames, complete risk management actions within specified time frames where warranted by the findings of the evaluations, and review and make determinations on Confidential Business Information (CBI) claims within specified time frames, among other actions.

- *Requirement to address risks.* EPA is required to take timely action to address risks identified in the risk evaluations by applying by rule one or more of the requirements specified in TSCA Section 6(a), which can include: prohibiting or restricting the manufacture, processing or distribution in commerce of the chemical substance or mixture for a particular use; limiting the amount of the substance or mixture that may be manufactured, processed or distributed in commerce for a particular use; or imposing requirements affecting labeling, recordkeeping or any manner or method of commercial use or disposal of the substance or mixture; to the extent necessary so that the chemical will no longer present an unreasonable risk.

- *Increased transparency of chemical data while protecting legitimate confidential information.* EPA is required to review all chemical identity Confidential Business Information (CBI) claims for certain types of submissions and for 25 percent of most other CBI claims within 90 days of receipt.

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[1] These include certain prevalent, high-risk chemicals known generally as "legacy chemicals" (e.g., PCBs, mercury), which were previously covered in a separate Chemical Risk Management (CRM) budget justification. The CRM program area was combined with Chemical Risk Review and Reduction effective FY 2015.

- *Requirement that EPA make an affirmative determination of safety on every new chemical.* Previously, new chemicals were allowed to enter the marketplace unless EPA made a specific determination that regulatory controls were needed. Now, continuing within the mandated 90-day timeframe, an affirmative determination must be made by EPA that a new chemical substance will present, may present, or is not likely to present an unreasonable risk to human health or the environment; or that the available information is insufficient to enable the Agency to make any of the above determinations. Unless EPA determines that the substance is not likely to present unreasonable risk, the Agency must issue an order or rule that imposes conditions sufficient to protect against any such unreasonable risk before the chemical can enter the marketplace.

In addition, amended TSCA provided a sustainable source of funding for EPA to carry out its responsibilities, authorizing the Agency to collect user fees designed to defray 25 percent of its costs for administering certain sections[2] of TSCA, as amended.[3] Fee levels may be adjusted on a recurring three-year basis for inflation and to ensure that fees defray 25 percent of relevant costs. TSCA User Fees began being incurred on October 1, 2018.

The statute authorizes EPA to collect fees from chemical manufacturers (including importers) and, in limited instances, processors who:

- Are required to submit information (TSCA section 4);
- Submit notification of or information related to intent to manufacture a new chemical or significant new use of a chemical (TSCA section 5);
- Manufacture, (including import) a chemical substance that is subject to an EPA-Initiated risk evaluation (TSCA section 6); or
- Request that EPA conduct risk evaluation on an existing chemical (TSCA section 6), subject to the Agency's approval of the request.

The Agency already has made considerable progress in carrying out work activities required under the amended law. Key achievements include:

- Commencing risk evaluations for the initial set of 10 chemicals, issuing scoping documents in accordance with statutory schedules, issuing problem formulation documents and initiating development of draft evaluations;
- Completing the first draft risk evaluation, for Pigment Violet 29, in November 2018;
- Finalizing all four key framework rules needed to carry out provisions of the amended TSCA law (Inventory Rule, Risk Evaluation Process Rule, Prioritization Process Rule, User Fees Rule);
- Releasing guidance for external parties interested in submitting draft risk evaluations to EPA for consideration;

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[2] The costs of implementing TSCA (as amended) Sections 4, 5 and 6 are defrayable up to the statutory caps, as are the costs of collecting, processing, reviewing and providing access to and protecting from disclosure, as appropriate, chemical information under Section 14.

[3] The authority to assess fees is conditioned on appropriations for the CRRR Program, excluding fees, being held at least equal to the amount appropriated for FY 2014.

- Completing reviews under the new law of more than 1,770 new chemical notifications and submissions[4] and utilizing a pre-submission consultation step to engage early with submitters;
- Enhancing chemical data transparency by issuing guidance for state, tribal, and local governments and emergency responders on sharing TSCA confidential business information (CBI), guidance on structurally descriptive names, and policy and procedures for assigning unique identifiers to improve public tracking of information on chemicals;
- Finalizing a strategy to reduce animal testing;
- Proposing a Significant New Use Rule (SNUR) requiring EPA review for new uses of asbestos before they can be allowed to be commercialized;
- Releasing for public comment a systematic review approach document to guide EPA's selection and review of studies and to explain how the agency plans to evaluate scientific information;
- Publishing an Interim List of Active Substances, as required by TSCA Section 8;
- Publishing a list of five mercury compounds that are to be made subject to export restrictions and a final rule on reporting mercury manufacturing and imports; and
- Conducting a series of public meetings and webinars to gather public input on TSCA implementation activities.

Future implementation activities will build on the progress EPA already has made.

FY 2020 Activities and Performance Plan:

Work in this program directly supports Goal 1/Objective 1.4 Ensure Safety of Chemicals in the Marketplace in the *FY 2018 - 2022 EPA Strategic Plan*. In FY 2020, the resources requested by EPA will support continued implementation of the amendments to TSCA, with emphasis on the critical mandates and timelines applicable to pre-market review of new chemicals, chemical risk evaluation and management, review and determinations on incoming CBI claims, and other statutory priorities. At the same time, the Agency will continue to carry out ongoing base program activities.

Primary TSCA Implementation Activities – TSCA Sections 4, 5, 6, and 14:

TSCA, as amended, provides mandates and authorities to EPA for implementation responsibilities under TSCA Sections 4, 5, and 6; for collecting, processing, reviewing, and providing access to and protecting from disclosure information on chemical substances as appropriate under TSCA Section 14; and to defray 25% of the costs of those activities through user fees. The amended statute also included a mandatory requirement for EPA to evaluate and manage existing chemicals with clear and enforceable deadlines; a new requirement that EPA make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before it is allowed to be commercialized; and increased public transparency for chemical information. This section describes activities associated with these mandates and authorities.

[4] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#chart

TSCA Section 4, as amended, authorizes EPA to require testing of a chemical substance or mixture by manufacturers (including importers) or processors. The 2016 TSCA amendments provided new test order and consent agreement authorities which are designed to expedite the Agency's collection of testing information for prioritizing and conducting chemical risk evaluations for new and existing chemicals. In FY 2020, EPA may utilize these authorities to require testing on chemicals in connection with the prioritization and risk evaluation processes, where such testing is needed. The Agency will continue to review test data submitted from prior test rules and enforceable consent agreements. As in past years, EPA will make use of Toxics Release Inventory (TRI) data in prioritizing chemicals for collection of testing information and evaluation of potential risks.

TSCA Section 4, as amended, also promotes the use of non-animal alternative testing methodologies. The Agency published an Alternative Testing Methods Strategy in June 2018, two years after the date of enactment, as required by the amended law, and began implementing the strategy.

Under TSCA Section 5, as amended, EPA is responsible for reviewing all new chemical submissions to determine whether the chemicals may pose unreasonable risk to human health or the environment if they were to enter U.S. commerce, and, when necessary, require restrictions or testing prior to being allowed to be commercialized. Each year, EPA assesses and manages, as necessary, the potential risks from approximately one thousand new chemicals, including nanoscale materials and products of biotechnology, prior to their entry into the marketplace. In FY 2020, the Agency will continue to implement the significant changes made to the new chemical review program by amended TSCA including the requirement that EPA make an affirmative determination of safety for each new chemical. EPA expects to review over one thousand new chemical submissions, take appropriate testing and risk management actions, including orders and SNURs where appropriate, and make affirmative determinations. The program also will evaluate the data submitted under requirements of Section 5 Consent Orders. In FY 2020, the Agency will continue to make improvements to internal data and tracking systems to address the mandates under TSCA as amended and to assess the new chemicals program for any further improvements stemming from lean projects undertaken by the program to identify potential steps to enhance the efficiency of the new chemical review process. These improvements will also provide regulatory relief to submitters by increasing certainty about timeframes for the reviews and associated risk management actions.

In addition, in FY 2020, EPA will continue to use TSCA Section 5 authorities to issue SNURs for existing chemicals, where applicable. The Agency has the authority to review and assess significant new uses of existing chemical substances. Upon receipt of a notification of a new use, the Agency initiates an evaluation focusing on the health and environmental effects of the substance's significant new use, makes a determination, and takes action, as appropriate, to address any unreasonable risks associated with the significant new use.

Under TSCA Section 6, as amended, EPA is required to maintain an ambitious schedule for initiating and completing chemical risk evaluations of existing chemicals. Where risks are identified, timelines are delineated for initiating and completing regulatory actions to address those risks.

- *Chemical Prioritization and Risk Evaluation*: In FY 2020, EPA expects to complete risk evaluations for the first 10 chemicals to undergo risk evaluation under the amended law (Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, 81 FR 91927). The statute requires documents identifying the scope of those evaluations within six months and completion within three years. Scoping and problem formulation documents for all 10 evaluations were released by EPA in June 2017 and June 2018, respectively. The Agency is continuing to advance these risk evaluations through the draft, peer review/public comment and final stages, with a goal of completion no later than December 2019, in accordance with statutory timelines. As noted previously, the first draft risk evaluation for Pigment Violet 29 was released in November 2018. In accordance with the statutory schedule, EPA plans to publish final risk evaluations for all ten chemicals by December 2019.

  For EPA-initiated risk evaluations beyond the first 10 chemicals noted above, EPA must first undertake a risk-based prioritization process to determine which chemicals will be evaluated, identifying them as either "high" or "low" priority substances for evaluation as set forth in TSCA section 6(b)(1)(A). EPA established this statutorily required prioritization process in a final rule published in July 2017. EPA sought public comment on potential approaches to inform the identification of potential candidate chemicals for this prioritization process and issued a white paper in September 2018, entitled "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization" describing the agency's plans for prioritization.

  A high-priority designation is required when EPA determines, without consideration of cost or other non-risk factors, that the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and a route of exposure, including to susceptible subpopulations (TSCA section 6(b)(1)(B)). A high-priority designation triggers a requirement that EPA begin and conclude a risk evaluation within three years to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation. [TSCA section 6(b)(4)(F)].

  EPA is required to commence a risk evaluation for an additional high-priority substance each time a risk evaluation is completed so that EPA maintains a pace of 20 EPA-initiated risk evaluations underway from the end of calendar year 2019 forward [TSCA section 6(b)(2)]. Accordingly, in FY 2020, the Agency will commence risk evaluations for an additional 20 high-priority chemicals after the expected completion of the first 10 evaluations in December 2019, based on the results of the prioritization process discussed above for identifying 20 high-priority chemicals. The law also directs the Agency to designate at least 20 chemicals, by the end of calendar year 2019, as low-priority substances, for which risk evaluation is not warranted at this time – also based on the results of the prioritization process discussed above.

The law includes provisions allowing manufacturers to request EPA to conduct evaluations of specific chemicals. EPA is required to undertake manufacturer-requested risk evaluations that meet the Agency's acceptance criteria at levels up to 50 percent of the number of EPA-initiated evaluations underway.

- *Risk Management:* When unreasonable risks are identified in the final risk evaluation, EPA must finalize risk management actions (rulemakings under TSCA Section 6(a)) to address the unreasonable risk within two years, or up to four years if an extension is utilized. Accordingly, the agency may be initiating risk management actions in FY 2020 for chemicals which have been found to present an unreasonable risk, based upon the first ten risk evaluations that must be completed in FY 2020. The statute provides a suite of risk management tools that can be implemented (alone or in combination) to address unreasonable risks associated with a chemical substance that has undergone risk evaluation and requires EPA to consider availability of technically and economically feasible alternatives when determining appropriate action to address risks. Implementation of the selected risk management action(s) must begin as quickly as possible, but no later than five years after promulgation of the final regulation.

  TSCA Section 6(h) establishes a fast-track process to address certain persistent, bioaccumulative, and toxic (PBT) chemicals on the 2014 TSCA Work Plan. For these chemicals, unless a manufacturer requests that they undergo a risk evaluation, a risk evaluation is not required, and action to address risks and reduce exposure to the extent practicable must be proposed no later than three years after enactment of the Lautenberg amendments (i.e., by June 2019) and finalized within18 months. EPA determined that seven chemicals on the 2014 TSCA Work Plan met the PBT criteria set forth in the amended law and subsequently received a manufacturer's request that two be evaluated under TSCA section 6. EPA is developing the PBT regulation based upon peer-reviewed exposure and use assessments for the five remaining PBT chemicals and expects to propose a regulation within the period prescribed by the law.

  In January 2017, EPA issued a proposed rule under Section 6(a) of amended TSCA, to regulate methylene chloride and N-methylpyrrolidone in paint and coating removal. The Agency had identified the risks posed by methylene chloride when used in paint removers in a final risk assessment released in 2014 ("[HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment-methylene"]."). This final assessment followed an extensive process of public drafts and peer review. EPA expects to continue work on regulating certain uses of methylene chloride in paint and coating removal in FY 2020. A follow-up rule on remaining uses of methylene chloride will be proposed if the agency's ongoing risk evaluation of methylene chloride under amended TSCA determines that additional uses of the chemical present unreasonable risks.

TSCA Section 14, as amended, makes significant changes to the CBI process, including:

- Establishing new substantiation requirements for certain types of confidentiality (CBI) claims from submitters;

- Requiring EPA to review and make determinations on many new CBI claims for the identity of chemicals and a subset of other types of CBI claims;
- Directing EPA to develop policies and procedures for sharing TSCA CBI with states, tribes, health and medical professionals, first responders, and others;
- Requiring EPA to review CBI claims for chemical identity relating to active chemical substances in commerce to determine if they are still warranted; and
- Directing EPA to establish guidance for structurally descriptive generic names that must be provided when specific chemical identity is claimed as CBI.

In order to comply with these provisions, EPA has developed an information management application to accommodate tracking of CBI reviews and continues to improve the agency's electronic reporting applications to increase compliance at the time of submission.

Other TSCA Mandates and Activities

TSCA Section 8: In March 2017, as required under Section 8 of TSCA, as amended, EPA published in the Federal Register an initial inventory of supply, use and trade of mercury and mercury compounds in the U.S., to be updated every three years. EPA will publish the next mercury inventory in FY 2020. In June 2018, as required under TSCA Section 8 to assist the preparation of future inventories, the Agency promulgated a rule establishing reporting requirements for persons who manufacture or import mercury and mercury-added products, or intentionally use mercury in a manufacturing process. Implementation of this rule will be ongoing in FY 2020. In FY 2020, EPA will maintain the Mercury Electronic Reporting application, an electronic reporting interface and database within the Central Data Exchange (CDX), EPA's electronic reporting system, and conduct outreach to instruct potentially affected stakeholders on how to report required information.

Also under Section 8, the Agency typically receives and analyzes about 300 Substantial Risk Notifications submitted by industry annually pursuant to Section 8(e), which requires EPA be notified immediately when a company learns that a substance or mixture presents a substantial risk of injury to health or the environment. EPA may use the information it receives in 8(e) notices in determining whether to take further action.

Under Section 8 of TSCA, as amended, EPA is required to designate chemical substances on the TSCA Chemical Substance Inventory as either "active" or "inactive" in U.S. commerce. To facilitate this, EPA, as required by law, promulgated a rule one year after enactment requiring industry to report chemical substances on the TSCA Inventory that were manufactured (including any that were imported) for non-exempt commercial purposes during the ten-year time period prior to enactment. Reporting began during the last quarter of FY 2017, with a 180-day timeline for manufacturers, followed by additional time for processors. EPA is using notices received to identify reported substances as active on the TSCA Inventory. Substances for which no notices are received will be identified as inactive on the Inventory. EPA expects to publish the first TSCA Inventory with active and inactive designations by the end of the first quarter of FY 2019. TSCA Section 8, as amended, also requires the Agency to promulgate a rule that establishes a plan for reviewing claims to protect confidential chemical identities reported in retrospective activity notices. The review plan rule must be published within one year of compiling the initial Inventory

with active and inactive designations. CBI claims made by manufacturers or processors for chemical identities in retrospective activity notices must be reviewed and determinations made no later than five years after compiling the initial Inventory. The current Inventory has approximately 7,750 chemicals on the confidential portion that have been reported as being active in commerce in the last 10 years.

Section 8 of TSCA also requires both manufacturers and processors to notify EPA in the future when they anticipate re-introducing into U.S. commerce substances listed as inactive on the TSCA Inventory. This future reporting will commence after the publication of the TSCA Inventory with active and inactive designations.

Other TSCA Activities: The Mercury Export Ban Act[5] prohibits the export of elemental mercury. Section 12 of TSCA, as amended, prohibits from export certain specific mercury compounds as of January 1, 2020 and directs EPA to publish a list of the compounds that will be subject to export bans. The Agency completed this step in FY 2016. Every five years, the Agency also must submit a report to Congress addressing any continuing export of those mercury compounds for exempted disposal activities, with recommendations as to whether further regulation is warranted. EPA will continue to provide responses to any requests for exemption from applicable export prohibitions and work necessary to support compliance with the Minamata Convention on Mercury, to which the United States is a party.

In FY 2020, EPA will continue to meet the requirements of Section 21 of TSCA, as amended, which authorizes citizen petitions for the issuance, amendment or repeal of certain actions (rules and orders) promulgated under TSCA: §4 (rules and orders requiring chemical testing); §6 (rules imposing risk mitigation controls on chemicals); §8 (rules requiring submission of information); §5 (orders affecting new chemical substances). Since September 2007, 23 citizen petitions have been filed with EPA under this authority. The Agency must grant or deny a Section 21 petition within 90 days; if EPA grants a petition, the requested action must be initiated in a timely fashion.

In FY 2020, EPA will continue implementing regulations under the TSCA Title VI Formaldehyde Standards for Composite Wood Products Act (Public Law 111-199), which established national emission standards for formaldehyde in new composite wood products.[6]

In FY 2020, the Agency will continue implementation of required TSCA Title IV activities These activities make significant contributions to protecting children's health by helping to reduce the number of children with blood lead levels of five micrograms per deciliter or higher[7] and to reduce the disparities in blood lead levels between low-income children and non-low-income children.[8].

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[5] MEBA prohibits the export of elemental mercury as of January 1, 2013, among other requirements for the EPA, DOE, and other federal agencies.

[6] See [HYPERLINK "http://www2.epa.gov/formaldehyde/formaldehyde-emission-standards-composite-wood-products"]

[7] Jacobs, D.E.; Clickner, R.P.; Zhou, J.Y.; Viet, S.M.; Marker, D.A.; Rogers, J.W.; Zeldin, D.C.; Broene, P.; and Friedman, W. (2002). The prevalence of lead-based paint hazard in U.S. housing. Environmental Health Perspectives, 110(10): A599-A606

[8] Centers for Disease Control and Prevention. Fourth Report on Human Exposure to Environmental Chemicals, Updated Tables, (September, 2012). Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. http://www.cdc.gov/exposurereport/

- Providing firm and individual certifications for safe work practices for lead-based paint abatement and renovation, repair, and painting efforts; providing operation and maintenance of the online database (FLPP)[9] that supports the processing of applications for training providers, firms and individuals; and continuing efforts to increase the number of certified renovation firms capable of providing lead-safe renovation, repair, and painting services through targeted outreach campaigns to contractors.

- In accordance with an order from the Ninth Circuit Court of Appeals, EPA published a proposed rule in the Federal Register on July 2, 2018, to change the dust-lead hazard standard from 40 µg/ft2 and 250 µg/ft2 to 10 µg/ft2 and 100 µg/ft2 on floors and window sills, respectively. EPA did not propose to change the post-abatement clearance levels in this proposal; however, the Agency noted that it intended to review the clearance levels at a later date. The court also ordered the Agency to propose a rule on the definition of lead-based paint. In the proposal, EPA proposed to make no change to the definition of lead-based paint because the Agency currently lacks sufficient information to support such a change. In FY 2020, EPA will continue work as necessary to determine if the definition of lead-based paint should be changed as well as if changes to the clearance levels are necessary.

- Per a settlement agreement, in FY 2020, EPA will continue to work on determining the extent to which renovations of pre-1978 public and commercial buildings do or do not create lead-based paint hazards and develop appropriate work practice standards to the extent they are deemed necessary.

Information Technology (IT) in Support of TSCA Implementation

- In line with the President's Management Agenda, a goal of TSCA IT systems development will be to minimize reporting burdens on industry, and streamline data management by EPA;

- Continuing enhancement of the TSCA Chemical Information System (CIS) to reduce manual handling of data, increase internal EPA access to data relevant to chemical assessments, and expedite review of chemicals;

- Continuing integration of TSCA information management, e-Reporting and public access systems with the Agency's E-Enterprise business strategy, leveraging the E-Enterprise portal to provide better customer service for external users;

- Developing new tools for hazard and exposure identification assessment and characterization, while improving existing tools to better assess risks from both new and existing chemicals;

[9] [HYPERLINK "https://ssoprod.epa.gov/sso/jsp/flppLogin.jsp"]

- Maintaining and enhancing the functionality of ChemView and expanding the information it makes available to the public to include newly completed chemical assessments, worker protection information and other new data reported to EPA under TSCA (e.g., Section 5 Pre-manufacture Notices (PMNs), Section 12(b) data, and Section 8 (d), 8(e), and 8(c) submissions).

In FY 2020, the Agency will monitor and evaluate its progress on key metrics related to carrying out its core responsibilities under the amended law in a timely manner. These include TSCA-related external long-term performance goals, annual performance goals and two-year Agency Priority Goals, supported by internal monthly tracking systems. In accordance with these goals, EPA expects to complete all EPA-initiated risk evaluations and all associated risk management actions for existing chemicals within statutory timelines. In addition, EPA plans to ramp up its performance on reviewing new Pre-manufacture, Microbial Commercial Activity, and Significant New Use Notices so that by FY 2022, EPA will aim to make 80% of all final determinations within the initial 90 day review period.

In addition to performance monitoring, EPA will undertake other forms of assessment and evidence gathering in FY 2020. The Agency's ongoing risk evaluation processes for existing chemicals utilizes scientific evidence obtained from data gathered pursuant to TSCA authorities and systematic review of literature sources in making the risk determination required under amended TSCA. EPA's approach to systematic review is described in "Application of Systematic Review in TSCA Risk Evaluations" (May 2018). Additional evidence will be obtained by completing an annual programmatic risk assessment exercise and a statutorily required OIG audit of TSCA user fees to determine whether fee levels are appropriate.

Performance Measure Targets:

FY 2020 Change from FY 2019 Annualized CR (Dollars in Thousands):

- ($/ FTE) This reflects an increase to support the implementation of efforts to meet statutory deadlines for prioritization, risk evaluation and risk management of existing chemicals and to streamline and accelerate the review of premanufacture and significant new use notices for new chemicals.

Statutory Authority:

Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (enacted June 2016).